

UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF TENNESSEE  
NORTHEASTERN DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	
	)	Case No. 2:21-CR-00008
	)	
[1] THOMAS K. WEIR	)	
	)	JUDGE TRAUGER
[3] WILLIAM L. DONALDSON	)	
	)	
[4] PAMELA SPIVEY	)	

**UNITED STATES' OPPOSITION TO DEFENDANTS' JOINT MOTION IN LIMINE  
NUMBER ELEVEN (MOTION TO EXCLUDE REFERENCES TO OPIOID EPIDEMIC)**

The United States of America, through Henry C. Leventis, United States Attorney for the Middle District of Tennessee, and Assistant United States Attorneys Sarah K. Bogni and Nani M. Gilkerson, hereby presents a response in opposition to defendants' joint motion to exclude references to opioid epidemic. (DE #272.) In their motion, defendants ask the Court to exclude any references to an opioid epidemic, or agency reactions and responses to the epidemic, as irrelevant or unfairly prejudicial. For the reasons set forth below, the Court should deny the motion or withhold on ruling on the motion at this time.

**RELEVANT BACKGROUND AND PROCEDURAL HISTORY**

The defendants are charged in this case with a conspiracy to illegally dispense controlled substances, in violation of Title 21, United States Code, Section 846, conspiracy to commit health care fraud and health care fraud in violation of Title 18, United States Code, Sections 1349 and 1347,<sup>1</sup> and defendants Weir and Donaldson are charged with a conspiracy to defraud the United

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<sup>1</sup> Defendant Donaldson is charged in the health care fraud conspiracy, but is not charged in the substantive counts at Counts 3 through 6.

States and violate the Anti-Kickback Statute, in violation of Title 18, United States Code, Section 371, all in connection with defendants' operation of and activities related to Dale Hollow Pharmacy and Clay County Xpress Pharmacy, in Celina, Tennessee, between 2014 and 2019. (DE #3.)

On January 16, 2024, defendants moved to exclude all references to an opioid epidemic or government agency responses to the epidemic. (DE #272.) In the motion, the defendants argue that such evidence is irrelevant because references to the opioid epidemic does not speak to whether defendants knowingly and intentionally dispensed controlled substances without authorization. Defendants are mistaken. Alternatively, the defendants argue the evidence should be excluded under Rule 403 because it will inflame the jury and imply it is their duty to combat the epidemic, suggest the pharmacy industry is at fault for the epidemic, or that there is no legitimate purpose for opioids.<sup>2</sup>

### **ARGUMENT**

As a threshold matter, the United States does not intend to reference an “opioid epidemic” or “opioid crisis” in its opening or its closing, or to argue that the mere act of operating a pharmacy that dispenses opioids contributes to the epidemic, or to suggest that the defendants or their co-conspirators contributed to an opioid epidemic.<sup>3</sup> Neither the Court nor the United States know

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<sup>2</sup> The motion also argues that suggesting involvement in the pharmacy industry in light of the opioid epidemic is somehow prohibited “bad acts” evidence under Rule 404(b). It is entirely unclear how references to an opioid epidemic constitutes an “other act” or “bad act” or suggests propensity in any way, and the defendants have not cited to any law to help explain their argument.

<sup>3</sup> Defendant’s motion indicates “[s]pecifically the government has indicated that it will seek to introduce such evidence.” (DE #272 at 1.) The defendants do not cite to a source for this assertion and the United States is not sure where it has specifically indicated an intent to introduce such evidence or argument.

what specific defense(s) might be raised at trial. The defendants have not produced any reciprocal discovery to the United States and despite having the United States' proposed exhibits for three months, have not provided their own exhibits. As a result, the United States does not know whether references to the opioid epidemic will even be presented at trial. Because of this, it would be premature for the Court to rule on the motion at this time.

However, should it be presented at trial, the United States expects co-conspirators may testify that they were aware of an opioid epidemic, and in particular, widespread drug abuse in Celina, Tennessee, and that they dispensed illegally from the pharmacy. Likewise, the United States anticipates its experts may testify about increased scrutiny and changes in dispensing practices and relevant laws that constitute part of the "usual course of professional practice" as a result of the widespread abuse and diversion of opioids, of which the defendants were aware during the course of the charged conspiracy. Lastly, the United States expects evidence, including materials seized from the pharmacies and testimony of lay witnesses who observed the pharmacies, may reference the opioid epidemic and the defendants' and co-conspirators' awareness of an epidemic. All of this evidence is probative of the crimes charged, namely, the defendants' subjective knowledge or intent to conspire to illegally dispense controlled substances and to submit fraudulent claims to Medicare and TennCare for medically unnecessary controlled substances, including but not limited to opioids.

**I. References to the Opioid Epidemic Should Be Admissible Because The Evidence Is Directly Relevant To The Crimes Charged**

The evidence is admissible because it tends to prove a fact of consequence, namely, the defendants' knowledge, which goes to willfulness and their intent to commit the charged offenses. *See* Fed. R. Evid. 401. "The standard for relevancy is 'extremely liberal' under the Federal Rules of Evidence." *Dortch v. Fowler*, 588 F.3d 396, 400 (6th Cir. 2009) ("Evidence is relevant if it has

“any tendency to make the existence of *any* fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” (emphasis added)). “Even if a district court believes the evidence is insufficient to prove the ultimate point for which it is offered, it may not exclude the evidence if it has the slightest probative worth.” *United States v. Sumlin*, 956 F.3d 879, 888 (6th Cir. 2020) (internal quotations omitted) (emphasis in original).

Relevant evidence is generally admissible subject to a few exceptions. *See* Fed. R. Evid. 402. Given that the evidence does not implicate Rule 404(b), the only real applicable exception here is under Rule 403. That rule “balances the probative value of relevant evidence against the ‘danger of unfair prejudice, confusion of the issues, or misleading the jury.’” *United States v. Seymour*, 468 F.3d 378, 385 (6th Cir. 2006). “Evidence that is prejudicial only in the sense that it paints the defendant in a bad light is not unfairly prejudicial pursuant to Rule 403.” *United States v. Sanders*, 95 F.3d 449, 453 (6th Cir. 1996); *see also United States v. Mullins*, 22 F.3d 1365, 1373 (6th Cir. 1994). “The test is strongly weighted toward admission,” *United States v. Asher*, 910 F.3d 854, 860 (6th Cir. 2018), and any potential prejudicial effect can be substantially mitigated by an instruction concerning the manner in which the evidence can be considered. *United States v. Hopper*, 436 Fed. App’x 414, 422-23 (6th Cir. 2011).

The Supreme Court’s recent decision in *Ruan v. United States*, 142 S. Ct. 2370, 2375 (2022), clarified that in an illegal dispensing or prescribing case charged under 21 U.S.C. § 841(a)(1), the United States must prove—at trial—that a defendant “knowingly or intentionally” acted outside the scope of his or her authorization under the Controlled Substances Act (“CSA”). The CSA instructs, in part, that, “except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.” 21 U.S.C. § 841(a)(1).

Dispensing a controlled substance is “authorized,” and therefore excepted from the statutory prohibition, when “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a);<sup>4</sup> *Ruan*, 142 S. Ct. at 2375. Authorization for a pharmacy stems from its DEA Registration, which requires compliance with the CSA and its regulations. Outside the usual course of professional practice not for legitimate medical purpose comes from the Code of Federal Regulations as it applies to providers authorized to dispense controlled substances. 21 C.F.R. § 1306.04 & 1306.06.

After *Ruan*, “the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so.” *Ruan*, 142 S. Ct. at 2375. *Ruan*’s scienter requirement is an “additional element” the government must prove. “[T]he crime of unauthorized distribution includes as an element that the defendant subjectively knew the distribution was unauthorized; that is, it is not sufficient that the distribution was objectively unauthorized.” *United States v. Bauer*, 82 F.4th 522, 527 (6th Cir. 2023) (citing *Ruan*, 142 S. Ct. at 2374); *United States v. Murphy*, No. 520CR291LSCSGC1, 2023 WL 2090279, at \*2-3 (N.D. Ala. Feb. 17, 2023) (citing *Ruan*, 142 S. Ct. at 2374.) (“[t]he *Ruan* cases compel the conclusion . . . that [the jury] must find that Dr. Murphy knew or intended that his prescription was unauthorized—that is, without a legitimate medical purpose or outside the usual course of professional practice. . . .”).

This case charges a conspiracy to illegally dispense, which already requires a finding that the defendants acted with subjective knowledge. Here, “for the conspiracy count, the matter at issue [i]s whether there was an agreement to violate drug laws and whether [defendants] knew

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<sup>4</sup> The responsibility for proper prescribing lies with the prescriber but a corresponding responsibility lies with the pharmacist who fills the prescription. 21 C.F.R. § 1306.04(a).

of, intended to join and participated in the conspiracy.” *United States v. Neuhausser*, 81 Fed. App’x 56, 65-66 (6th Cir. 2003); *Murphy*, 2023 WL 2090279, at \*3 (upholding conviction under 21 U.S.C. § 846 even in light of *Ruan* because the conspiracy instructions require the jury to find a defendant acted with subjective intent) (citing *United States v. Ruan*, 56 F.4th 1291, 1299 (11th Cir. Jan. 5, 2023)).

Thus, evidence as to what constitutes the usual course of professional practice as well as what these defendants and their co-conspirators were on notice of and directly aware of is highly probative. “[T]he Government, of course, can prove knowledge of a lack of authorization through circumstantial evidence.” *Ruan*, 142 S. Ct. at 2382. As the Sixth Circuit explained in *Bauer*, “the Court was careful not to bar all consideration of objective criteria. The relevant regulation language—‘legitimate medical purpose’ and ‘usual course’ of ‘professional practice’—reflects that objective criteria are still relevant to the extent they are circumstantial evidence of a defendant’s knowledge of lack of authorization.” *Bauer*, 82 F.4th at 528 (citing *Ruan*). What constitutes the usual course of professional practice for legitimate medical purposes comes from professional standards governing the dispensation of controlled substances. *United States v. Hoffman*, 2006 WL 3691487 at \*4 (D. Me. Dec. 12, 2006) (government may introduce Massachusetts medical board rules and regulations because “it is relevant to aid the jury in assessing what constitutes a legitimate medical purpose and the usual course of professional practice.”) “[E]vidence that a physician consistently failed to follow generally recognized procedures tends to show that in prescribing drugs he was not acting as a healer but as a seller of wares.” *United States v. Alerre*, 430 F.3d 681, 691 (4th Cir. 2005). Objective evidence remains important for the government to meet its burden.

Such evidence includes the risk of opioids and the heightened scrutiny around opioids due to the opioid epidemic and how that fact changed the usual course of professional practice. As such, post *Ruan* courts have acknowledged the value of such testimony. *Bauer*, 82 F.4th at 529 (finding substantial circumstantial evidence defendant intended to act in unauthorized manner including through government expert testimony and stating “while direct evidence was lacking, the compounding of this circumstantial evidence ‘especially as measured against objective criteria’ allows an inference that Bauer had subjective knowledge”); *United States v. Kraynak*, No. 4:17-CR-00403, 2022 WL 3161907, at \*3 (M.D. Pa. Aug. 8, 2022), *aff’d*, No. 22-2500, 2023 WL 4636419 (3d Cir. July 20, 2023). In *Kraynak*, the government’s medical expert testified about how the Centers for Disease Control and Prevention (“CDC”) recognized an opioid epidemic in 2011 and how that led to changed practices in how doctors were expected to treat patients and document prescribing. *Id.* Such testimony puts the usual course of professional practice in context in demonstrating that someone acted outside the usual course. Then the question becomes, was it knowing or intentional? *Id.* at \*8. As the court in *Kraynak* observed in citing *Ruan*:

The Government, of course, can prove knowledge of a lack of authorization through circumstantial evidence.” The Supreme Court noted that “the regulation defining the scope of a doctor’s prescribing authority does so by reference to objective criteria such as ‘legitimate medical purpose’ and ‘usual course’ of ‘professional practice’ ” and emphasized that “ ‘the more unreasonable’ a defendant’s ‘asserted beliefs or misunderstandings are,’ especially as measured against objective criteria, ‘the more likely the jury will find that the Government has carried its burden of proving knowledge.’

*Id.* The relevant objective medical standards governing the practice of pharmacy has unavoidably been influenced by the opioid epidemic, which existed well before the charged conspiracy in this case, thus influencing the usual course of professional practice for the charged

timeframe and it thus should be admissible.<sup>5</sup> That said, the government intends to discuss the “opioid epidemic” only in relation to the context it might provide to the admissible evidence in defendant’s case: for example, when discussing a testifying law enforcement witness’s training and experience in identifying “red flags,” providing context for the applicable standard of the usual course of professional practice, or descriptions of what Medicare and TennCare deems medically necessary or eligible for reimbursement and actions taken to avoid scrutiny by these insurance programs.<sup>6</sup> Even pre-*Ruan* case law supports this approach. See *United States v. Bynes*, No. 4:18-cr-153, 2019 WL 4734598, at \*2 (S.D. Ga. Sept. 26, 2019) (permitting the government to elicit testimony or present argument referring to the crisis or epidemic only as relevant context for otherwise admissible evidence, such as in establishing or informing the applicable standard of care) (citing *United States v. Minas*, 697 Fed. App’x 531, 532 (9th Cir. 2017) (finding admissible expert testimony about a policy “adopted ... in part because of concerns over Idaho’s opioid epidemic”)); *United States v. Feldman*, No. 8:14-cr-521, 2016 WL 3002418, at \* 5 (M.D. Fla. May

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<sup>5</sup> For example, the expert in *Kraynak* testified about the CDC putting out guidance as a result of the opioid epidemic in 2011. Experts in this case may testify that additional guidance was released in 2016, as well as a black box warning by the FDA regarding combinations of controlled substances with opioids. Likewise, Tennessee codified its existing guidance on the prescribing and dispensing of buprenorphine in 2015. In direct response to the opioid epidemic, Tennessee released Chronic Pain Guidelines to provide guidance on the professionally accepted standards for opioids and other controlled substances. Widely publicized and disseminated as accepted standards, the very preamble to the 2014 guidelines, written by the Tennessee Commissioner of Health, states “our nation now clearly recognizes the epidemic of substance abuse and misuse driven by prescription opioids.” In recommending practice guidelines regarding the dispensation of opioids, it goes on to state optimistically “this is not the first such epidemic in our nation’s history. We have our best chance this time however, to make it the last.” All of these guidelines were well known and governed the usual course of professional practice during the charged conspiracy period.

<sup>6</sup> Medicare and TennCare issued guidance on reimbursement for opioids as well, and its rules on require pharmacies to act in accordance with standards of professional practice and dispense for legitimate medical purposes.



20, 2016) (finding that reference to an “epidemic of prescription drug abuse ... was certainly relevant to put this case in its proper perspective”).<sup>7</sup> Thus, evidence that the defendants and co-conspirators violated objective standards that have been in place in part due to the opioid epidemic, indicates the defendants acted knowingly. *Kraynak*, 2022 WL 3161907, at \*9.

In addition to experts, the United States will also call law enforcement agents who will testify that they seized copies of laws, rules, regulations, policies, and trainings from the pharmacies, putting the defendants directly on notice of the heightened scrutiny of opioid dispensing because of abuse and diversion. Possession of the materials is strong circumstantial evidence of knowledge of their contents. Likewise, the United States anticipates that some witnesses, including co-conspirator pharmacists and employees of the pharmacies, may testify to their awareness of the opioid epidemic at the time of the charged conduct in this case and how it impacted their own actions. As court’s have acknowledged, the opioid epidemic has hardly been a little known or unpublicized fact. *United States v. Garrison*, 888 F.3d 1057, 1059 (9th Cir. 2018) (noting that “in 2017, the Acting Secretary of Health and Human Services declared the national opioid abuse epidemic a public health emergency”).

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<sup>7</sup> Defendants cite only to a pre-*Ruan* opinion in *United States v. Robinson*, No. 16-98, 2017 U.S. Dist. LEXIS 106729, \*1 (D.D.C. July 11, 2017) (no Westlaw citation available), in support of their assertion that there is inherent prejudice in specifically referencing the “opioid epidemic.” However, the court in *Robinson* said nothing of the sort. In response to a motion in limine to exclude such references, the United States indicated it had no intention of doing so and the Court rendered the motion largely moot. The United States expressed that its expert would testify about the “prevalence of opioid use” and a pharmacist would testify about seeing increased opioid prescriptions, but witnesses would not say “opioid crisis” or “opioid epidemic.” As such, the Court did not engage in any meaningful analysis of relevant evidence.

Lastly, lay witnesses may testify about their observations of the operation of the pharmacy and why, in part based on their own experiences with the opioid crisis as pharmacists, they recognized red flags of abuse and diversion that would be obvious to the defendants.<sup>8</sup>

The evidence that the United States intends to offer is relevant. Evidence in the form of expert testimony, documents taken from the pharmacies, or the testimony of witness that indicates defendants were aware of an opioid crisis or opioid epidemic places direct knowledge into the minds of the defendants that they were not operating in compliance with the law. Such evidence is highly probative.

## **II. There Is No Unfair Prejudice.**

The defendants argue that this evidence should be excluded under Rule 403 because it is unfairly prejudicial. (DE #272 at 3-4.) This argument lacks merit as well. Rule 403 provides that relevant evidence may be excluded “if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” Fed. R. Evid. 403; *see United States v. LaVictor*, 848 F.3d 428, 445 (6th Cir. 2017); *United States v. Churn*, 800 F.3d 768, 779 (6th Cir. 2015). All evidence offered to prove a crime, of course, “is to some extent prejudicial” to the defendant. *United States v. Talley*, 164 F.3d 989, 1000 (6th Cir. 1999). Importantly, however, although evidence may be *unfairly* prejudicial for purposes of Rule 403 if it invites the jury to decide the case “on an improper basis,” it is not unfairly prejudicial if “it only damages the defendant’s case due to the legitimate probative force of the evidence.” *United States v. Houston*, 813 F.3d 282, 291

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<sup>8</sup> For instance, one pharmacist witness may testify that he was so disturbed by the practices of the pharmacies that he repeatedly observed to himself and others that when at the pharmacies, he was in the center of the opioid crisis and that he repeatedly told co-conspirator and pharmacist-in-charge John Polston that he needed to leave Dale Hollow Pharmacy.

(6th Cir. 2016) (quotation marks omitted); see *In re Air Crash Disaster*, 86 F.3d 498, 538 (6th Cir. 1996) (“Rule 403 does not exclude evidence because it is strongly persuasive or compellingly relevant—the rule only applies when it is likely that the jury will be moved by a piece of evidence in a manner that is somehow unfair or inappropriate. The truth may hurt, but Rule 403 does not make it inadmissible on that account.”). Rule 403, furthermore, “is strongly weighted toward admission,” *United States v. Asher*, 910 F.3d 854, 860 (6th Cir. 2018), and exclusion of otherwise-admissible evidence under the rule “is an extraordinary remedy [that] should be used sparingly,” *United States v. Durham*, 902 F.3d 1180, 1224 (10th Cir. 2018) (quotation marks omitted).

The United States will not present evidence or argument that there are no legitimate uses for opioids and that the jury’s verdict should be based on an epidemic or national crisis rather than an individualized determination of the defendants’ actions. (DE #272 at 4.) The Government disagrees with these unsupported assertions and does not intend to “[m]ake this case about broader societal or national issues of concern;” suggest that because the defendants worked in the pharmacy industry, they caused the opioid epidemic; or imply to the jury that it is the juries’ responsibility or obligation to battle the opioid epidemic through their analysis of the evidence as it pertains to the defendants and the counts contained in the Indictment. (*Id.* at 2-4.)<sup>9</sup>

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<sup>9</sup> In many respects, the defendants’ motion appears to represent a continued failure of defendants to appreciate the charges in this case. For instance, the motion ignores that that proof at trial will include evidence of defendants’ and their co-conspirators illegal dispensing of buprenorphine, an opioid that, when prescribed, dispensed, and taken properly, is used as a medication assisted treatment for opioid addiction. As a result, there will be testimony about opioid abuse and addiction at trial in order to explain buprenorphine and how the pharmacies and defendants dispensed it outside the usual course of professional practice. Given the evidence of the enormous volume of ordering and dispensing of buprenorphine by the pharmacies, far outside comparable pharmacies even in the state of Tennessee, the United States would have anticipated that the defendants themselves would be embracing the opioid epidemic as part of its defense, arguing that the volume of buprenorphine dispensed by the pharmacies overtime was not illegal dispensing but merely an attempt to meet the demand presented by the opioid epidemic: scores of patients in need

But what is relevant is the context in which the conduct in this case occurred: pharmacies dispensing controlled substances during the years 2014-2019, including opioids, with the knowledge that the risks of abuse and diversion were great and that, as a result, scrutiny was high. The evidence is not unfairly prejudicial as it directly puts knowledge and intent in the minds of the defendants. In fact, admitting the evidence will provide greater context for the jury in assessing knowledge and intent. The United States will not argue that the defendants are the cause of the opioid epidemic or that the pharmacy industry in general is at fault for the opioid epidemic. The United States will also refrain from references to an opioid epidemic or opioid crisis in its opening and its closing. This Court should decline to exclude this evidence under Rule 403.

### **CONCLUSION**

For the reasons above, the government respectfully requests that this Court should deny the defendants' Motion in Limine Number Eleven (Motion to Exclude References to the Opioid Epidemic) (DE #272), or reserve ruling on the motion until and if the evidence is presented at trial.

Respectfully submitted,

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of buprenorphine to treat their opioid addictions. If defendants' motion is granted, the Court should prohibit defendants from referencing or presenting any evidence as to an opioid epidemic as well.

### **CERTIFICATE OF SERVICE**

I hereby certify that on February 5, 2024, I electronically served a copy of the motion with the Clerk of the Court by using the CM/ECF system, which will send a Notice of Electronic Filing to counsel for the defendants.

*s/ Sarah K. Bogni*

Sarah K. Bogni